

## INFORMATION SHEET FOR PARENTS /GUARDIANS



PROJECT TITLE:

## No visually impaired children undiagnosed in the world

Coordinator: Victoria Pueyo

Principal Investigator: XXXXXXXX Phone: XXXXXXXX

We invite your child to participate in a study that is being run at the XXXXXXXX Hospital in collaboration with seven centers from other countries. Your participation in the study is entirely voluntary. This project has been approved by the Local Institutional Review Board (XXXXXXX), but before taking any decision it is necessary that, as the mother/father/guardian of the child, you:

- read this entire document carefully
- understand all the information given in the document
- ask all the questions you consider necessary
- make a thoughtful decision
- sign the informed consent, if you finally want to participate
- if your child is already able to read, it is interesting him/her reading the information for the children that appears in this document.

If you want your child participating in the study, you will be given a copy of this information sheet and the signed informed consent document. Please keep it in case you may need it in future.

The main objective of the project is to create and train artificial intelligence algorithms to identify children with visual disorders as early as possible, through a visual test implemented in a device called DIVE.

#### Why are you invited to participate?

We request your child participation because we want to carry out a study in children of different ages and characteristics. Around 5000 children will participate in the study in one of the 6 centers participating in the project.

#### What is the study about?

The study involves two parts: during the first one we will explore the visual function of your child through a conventional ophthalmological exam, as it was scheduled for this

medical visit, and during the second part we will assess visual function using a digital test. All the tests that will be done are safe, non-invasive and pleasant for the child. The prenatal and postnatal life data of the child will be obtained from the medical records of the center.

#### What are the benefits of participating in this study?

By making an extensive study of the visual functions the child can benefit from the detection of certain problems that might otherwise have gone unnoticed. In those cases in which any alteration is found, you will be informed immediately and will be advised on the treatment or complementary study that the child may need.

#### Is there any risk for participating in the study?

There are no disadvantages or added risks for the child. The only additional explorations that will be performed will be the exam with the digital device, which is non-invasive and totally harmless.

#### What happens if you refuse to participate in the study?

The acceptance of your child's participation in the study is absolutely voluntary. You may change your mind later and refuse participating even if you agreed earlier.

#### How will my personal data be treated?

All the information gathered will be treated according to the current regulations of personal data protection. In the study database will not be included neither the name, nor the clinical history number, nor any data that allows identifying the participants. Your identifying information will be replaced by study codes. Only the research team will have access to information that identifies you.

According to the current regulations of personal data protection, you can exercise the rights of access, modification, opposition and cancellation of data. In addition, you can limit the processing of data that are wrong, request a copy or transfer to a third party (portability) the data that you have provided for the study. To exercise your rights, contact the principal investigator of the study. Likewise, you have the right to contact the Data Protection Agency if you are not satisfied.

If you decide to withdraw consent to participate in this study, no new data will be added to the database, but those that have already been collected will be used. In case you wish to destroy both the data and the samples already collected, you must request it.

The coded data can be transmitted to third parties in other countries but in no case will it contain information that allows direct identification of your child, such as name and surnames, initials, address or hospital codes. If this transfer occurs, it will be for the

described study purpose or for their use in scientific publications but always maintaining the confidentiality of them according to current regulations.

The researcher will guarantee the protection of privacy and will not allow their data to cross with other databases that could allow their identification or that are used for purposes unrelated to the objectives of this investigation.

The conclusions of the study will be presented in congresses and scientific publications, but they will always be made with gathered data and nothing that can identify you will never be disclosed.

#### What happens if I have any doubts during my participation?

At the beginning of this document, you can find the name and telephone number of the principal investigator responsible for the study. You can contact him in case you have any doubt about your participation.

Thank you very much for your attention, if you finally want to participate, please sign the attached informed consent document.

## INFORMATION FOR PARTICIPANT CHILDREN

We invite you to participate in a study in which children from all over the world will participate. None of the tests that we are going to do will be annoying for you and also we will finish the study using a tablet, where you will see some pictures and you will only be asked to look at them. Nobody will be able to match your results with your name, all the data from all the children will be treated together. It is likely that, with your help and all this information, we can improve the vision of children all around the world.

Thank you.

## INFORMED CONSENT DOCUMENT



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I, \_\_\_\_\_, as  
(mother/father/legal guardian) of the child: \_\_\_\_\_

- have read the information sheet that has been given to me,
- have been able to ask questions about the possible benefits and drawbacks of participating in the study, and have received enough information about it,
- understand that my participation is voluntary and that I can withdraw from the study at any time, without having to give explanations, and without having an impact on my subsequent medical care.
- have spoken with \_\_\_\_\_ (project researcher)
- freely want to participate in the study and give my consent for the access and use of my data as specified in the information sheet that has been given to me,
- have received a signed copy of this informed consent.

Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ Participant signature:

I have explained the nature and purpose of the study to the aforementioned patient.

Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ Researcher signature: